Nevada Medicaid

Pharmacy & Therapeutics Committee

Location of Meeting

401 South Carson Street, Room 2135, Carson City, NV

Teleconference

555 E. Washington, Room 4406 Las Vegas, NV

MINUTES OF March 25th, 2004 1:00 p.m.

Committee Members Carson City:

Steven Phillips, MD, Chairman Judy Britt, PharmD Carl Heard, MD Susan Pintar, MD Larry Pinson, PharmD

Committee Members Las Vegas:

Diana Bond, RPh Linda Flynn, RPh Robert Horne, MD Thomas Wiser, PharmD Alan Greenberg, MD

Others Present:

Darrell Faircloth AGO, Coleen Lawrence DHFCP, Nancy Davis DHCFP, Jeff Monaghan First Health Services Corporation, Kenneth Kolb, First Health Services Corporation, Dawn Daly First Health Services Corporation, Jamie Wyels First Health Services Corporation, Joseph Tyler, Advisory Committee, Carla Sloan AARP, Paul Pereira Tap, Steve Rossi Roche, June Oliver Nevada Care, Jay Pate MD CCN, K. Huffala RX Pharmacy Solutions, C. Goodwin Aventis, Greg Wittman Merck, Barbara Tagge CCSS, S. Spencer Roche, Pat Wilson National Silver Haired Congress, Thelma Clark NSHC, Charles Graham MD, Charlie Speranzo Novartis, Ann Cornish Aventis,

I. Call to Order and Roll Call

Chair Steven Phillips called the meeting to order at 1pm. All committee members were present.

II. Approval of Minutes of February 26th, 2004 meeting,

The chair requested that the site of the meeting in the minutes be changed from Reno to Carson City.

Motion to Accept: Dr. Pintar Seconded: Judy Britt Ayes: Unanimous Nayes: None

III. Presentation of DHCFP's Recommendations for a Preferred Drug List (PDL), based on Committee actions taken during the February meeting.

Dr. Phillips stated this will not occur at this meeting because they do not have the final recommendations from DHCFP.

IV. Approval of Drugs for PDL inclusion from February Drug Class Reviews

Dr. Phillips stated this will not occur at this meeting because they do not have the final recommendations from DHCFP.

V. Public Comment On March Class Reviews

Dr. Phillips stated the glaucoma agents will be taken as separate classes. Due to the public comment that the committee received Dr. Phillips clarified that the committee task was to review by class by specific agents and to make clinical judgements without considering cost.

Larry Pinson stated he was perplexed of the comments in the written comments they have received. He stated the committee was to establish equivalency and the state along with FHSC would come back with recommendations for the PDL. It is not the intent to leave something off that someone would need. Dr. Phillips stated there is confusion among the public, but wanted to stick to the agenda and would approach that subject at the end of the meeting. Dr. Phillips stated that a FAQ be developed to send out to those submitting comment.

VI. Glaucoma Agents

1. Alpha 2 Adrenergic Agents

Public Comment: Dawn Daly, FHSC read the names of written public comment that were submitted for all glaucoma agents.

Henry A. Hough, 60 Plus Assn-Documents attached.

Thelma Clark, Nevada Silver Hair Legislative Forum-Stated the Senior RX program would not fill her prescription and she would have to pay for it. She gave instances of seniors who's insurances would not pay for certain medications.

Dr. Gerald Hobson on behalf of Dr. Tom Conklin, Carson City-Reviewed the alpha adrenergic agents. He stated they were all effective agents.

2. Beta-Blockers

Public Comment: Dr. Gerald Hobson-Reviewed the beta-blockers and stated this group had more side effects but all are effective. Dr. Heard asked about Alphagan & Alphagan-P and if there were differences in them. Dr. Hobson said not really other than the preservative. Tom Wiser asked about the statistical difference in adverse effects. Dr. Hobson stated he did not have the exact clinical statistics.

3. Carbonic Anhydrase Inhibitors(CAI's)

Public Comment: Dr. Gerald Hobson-Reviewed the CAI's. Usually not good compliance in this class but they are effective agents.

4. Prostaglandin Agents (PA's)

Public Comment: Dr. Gerald Hobson-Reviewed the PA's. All PA's are extremely effective. He stated that this is becoming the first choice of therapy.

Gregory Whitman, MSD for the beta-blockers and CAI's. He stated he would be leaving package inserts. He stated the combination of these 2 agents dosing was more effective than a single agent alone.

Dr. Charles Graham-Document attached. He was asked about efficacy of PA's in the African-American population. Dr. Graham stated the studies were still on going and that they needed a larger population to study.

Dr. Phillips interjected they are reviewing classes for therapeutic equivalency. He stated that the committee will not deny any drugs that are not on the PDL, but there will be a prior authorization process to receive these drugs.

Joel Fain, Pfizer Medical-Gave an overview of Xalatan. Dr. Pintar asked if there were any studies in pediatrics. He answered no and the indication was for 17 years or older. Judy Britt asked about how they came up with the discontinuation rate statistics. He stated there is a way to pull this data from refill rates, PBMs and retail records.

Dan Eisenberg, Glaucoma specialist. He stated he has written articles on PA analogs and has lectured across the country. All are approximately the same efficacy and equivalency. Major difference is the hyperuremia(redness of the eye) caused by Lumigan and Travatan. The entire class does not work well in pediatrics. Tom Wiser asked if he received sponsorship from any manufacturers of these agents. Dr. Eisenberg stated yes.

The topic of disclosure by the public was brought up by Tom Wiser. Dr. Phillips stated they prefer to know that up front and do a better job of signage.

Tom Wiser asked why Rescula was dosed twice a day. Dr. Eisenberg stated it was a breakdown product.

Jeff Monaghan, FHSC-Gave an overview of all 4 glaucoma classes. He referred the committee to the letter from Dr. Michael Stanko in their packet. He was asked if they should consider the selective and non-selective beta-blockers as separate categories. The answer was no. Judy Britt asked what was the source of the discontinuation rate in the packet. He replied the references used were Micromedex and Facts & Comparisons.

No other public comment.

VII. Committee Discussion and Action for Glaucoma Agents by Class 1. Alpha 2 Adrenergic Agents

Judy Britt questioned the therapeutic equivalency of apraclonidine due to it side effects and limited clinical use. Judy Britt felt the agents in this class are not therapeutic equivalents Motion: Judy Britt motioned apraclonidine is not therapeutic equivalent and should be excluded from the class.

Seconded: Tom Wiser

Dr. Heard wanted clarification of the process. He stated therapeutic equivalents will achieve the same end result but could have different side effect profiles to consider. He asked to amend the motion to be therapeutically equivalent then exclude the drug. No modification was done. Tom Wiser asked Judy Britt for more explanation on why there drugs were not clinically equivalent. Judy Britt responded therapeutically she would not use this product and perhaps it is the semantics. She also stated it had limited use.

Votes: Ayes: Dr. Pintar, Judy Britt, Tom Wiser, Linda Flynn, Dr. Greenberg, Dr. Horne Nayes: Dr. Heard, Larry Pinson, Dr. Phillips, Diana Bond

Motion carries.

Discussion & adoptions of exclusions/exceptions for certain patient groups.

Ken Kolb asked for clarification since the previous motion was to exclude apraclonidine from the class. He stated the committee would need to establish therapeutic equivalency for the remaining alpha agents.

Motion; Dr. Horne motioned the remaining agents were therapeutically equivalent.

Seconded: Diana Bond

No discussion.

Votes: Ayes: Dr. Pintar, Dr. Phillips, Judy Britt, Larry Pinson, Tom Wiser, Diana Bond,

Dr. Greenberg, Dr. Horne, Linda Flynn

Naves: Dr. Heard

Discussion on exclusions or exceptions.

Ken Kolb clarified that an excluded drug the state could say it is non-preferred or unique and preferred. Dr. Pintar stated she thought when the state comes back with the list that is when the drugs would be determined to be preferred or non-preferred. Ken Kolb stated if you exclude a drug from the PDL it could be used more often.

Dr. Heard stated that the committee was there to debate whether the drugs in the specific classes were therapeutically equivalent. Ken Kolb stated the idea behind the motion would be to motion that the class is therapeutically equivalent except for X,Y,Z would work. The finance piece would

come in after that. He then said once a drug is excluded it can't be a preferred drug. If it becomes a non-preferred drug they can send it to the Drug Utilization Review Board (DUR) for PA criteria for it's use. Dr. Phillips said they could defer it to the DUR.

Motion: Diana Bond moved to give apraclonidine a non-preferred status and refer to the

DUR Board. Seconded: Larry Pinson

No Discussion.

Vote: Ayes: Unanimous

Exclusions or Exceptions. None

Prior Authorization Criteria; Defer until PDL is presented to committee.

Beta-Blockers

Motion: Tom Wiser moved the class is therapeutically equivalent.

Seconded; Diana Bond

Amended: Tom Wiser amended that the selective and non-selective be consider as a

group.

Seconded: Diana Bond

No Discussion.

Votes: Ayes: Unanimous
Exclusions or Exceptions: None
Prior Authorizations Criteria: None

Carbonic Anhydrase Inhibitors

Motion: Dr. Heard moved the class is therapeutically equivalent and include the

combination.

Seconded: Judy Britt

No discussion.

Vote: Ayes: Unanimous

Exclusions or Exceptions: Diana Bond stated there should be a provision for the use of Cospot and that criteria be developed. Dr. Phillips suggested if a patient was on a beta-blocker/CAI alone then a CAI/Beta-blocker was added then the combination could be used.

Motion: Diana Bond motioned the above criteria.

Seconded: Dr. Horne

Votes: Ayes: Unanimous

Prostaglandin Agonists:

Motion: Tom Wiser moved the class is therapeutically equivalent except for Rescula.

Seconded: Unknown

Dr. Horne amended that Rescula considered not necessary medication. Tom Wiser accepted the friendly amendment. Dr. Phillips cautioned the committee that they were putting Rescula in the same box as apraclonidine and did really want to do that. Jeff Monaghan suggested they consider all agents therapeutically equivalent and have FHSC come back with Prior Authorization (PA) criteria for the use of agents the committee would want to restrict, i.e. non-preferred agents. Dr. Phillips asked that the motion be restated. Tom Wiser did along with the friendly amendment. Jeff Monaghan at this time suggested an amendment to develop PA criteria based on value when the state & FHSC comes back with the drug selection.

Tom Wiser withdrew his motion.

Motion: Dr. Heard moved the prostaglandin agents be accepted as therapeutically

equivalent.

Seconded: Dr. Pintar

Motion: Dr. Horne proposed an amendment that PA criteria for Rescula be brought back to

the committee when the PDL is presented.

Seconded: Judy Britt

No discussion.

Votes: Ayes: Unanimous

VIII. Agents in the Treatment of Hepatitis Pegylated Interferons

Public Comment: Mary Wherry, DCHFP, stated the intent of the P&T committee is to determine therapeutic equivalency. The state will do financial analysis and come back to the committee with their suggestions. Drugs that do not make the PDL in their specific therapeutic class will still be available through a PA process. It is an open formulary in a sense, with non-preferred agents requiring prior authorization.

Dawn Daly, FHSC informed committee of the written comments submitted.

Steve Rossi, Roche-Gave an overview on Pegasys & Copegus. A committee member asked about toxicity in lower weight patients. His response was lighter patients don't tolerate the drug as well but have a better response rate.

Ann McDermott, RN-Works with hepatitis C agents. She stated no one product works for all patients. They need a choice.

Schering-Plough representative gave an overview of PEG-Intron.

Dr. Heard asked about PEG attachment and whether it was inert. SP response was yes. Judy Britt asked about the timeline of the head to head studies. His response was they just have completed selecting the sites and are looking for patient enrollment. Diana Bond inquired if one of those sites is in Nevada. He responded yes. She asked if he could disclose the site. He could not at this time. Dr. Phillips asked if when he knew if he could inform the committee. Diana Bond stated she is concerned from a conflict of interest standpoint.

Sharon Gonzalez from Schering-Plough. She asked Darrell Faircloth, DAG for his understanding of AB384. He explained to her that the P&T committee could decide to exclude a specific class of drugs from the PDL if they deemed it necessary. Dr. Phillips interjected that the classes the committee will be reviewing were approved by the committee at the February meeting.

Jeff Monaghan, FHSC gave the overview for the Pegylated interferons.

No questions.

Ribavirins

Public Comment: None

Jeff Monaghan, FHSC gave an overview for ribavirins.

IX. Committee Discussion and Actions for Pegylated Interons

Motion: Dr Heard moved to consider it a therapeutic equivalent class

Seconded: Larry Pinson

No discussion.

Votes: Ayes Unanimous

Exclusions or Exceptions: None Criteria for Prior Authorization: None

Motion: Diana Bond moved to that the ribavirins are therapeutically equivalent.

Seconded: Dr. Heard

No discussion.

Votes: Ayes: Unanimous

Recess

Dr. Pintar had to leave the meeting at the recess.

Tom Wiser & Judy Britt informed the committee that they would have to leave at 4pm. Dr. Phillips responded if they had a quorum the meeting would still continue.

Exclusions or Exceptions: None

Criteria for Prior Authorization: None

X. Low-sedating Antihistamines and Combinations

Public Comment: Dawn Daly informed the committee of the written public comment.

Jonathan Raap, Aventis-Gave an overview of Allegra. Dr. Heard asked about the combinations. The answer was the difference is the amount of pseudoephedrine.

SP Representative-Gave an overview of Clarinex.

Richard Morita, Pfizer-Gave an overview of Zyrtec.

Jeff Monaghan gave an overview of the drug class. Diana Bond asked how to handle the pediatric group. He responded that the pediatric population will be addressed when the committee is given the suggested drugs for the PDL.

XI. Committee Discussion and Actions for Low-Sedating Antihistamines and Combinations Motion: Diana Bond moved that the low-sedating antihistamines and combinations be considered therapeutically equivalent with the provision that the pediatric population will be considered.

Seconded: Tom Wiser

No discussion.

Votes: Ayes: Unanimous (Dr. Pintar was absent at this point)

XII. Beta-Blockers-Oral Agents

Public Comment: Dawn Daly informed the committee of the written public comments that were submitted.

Penny Atwood, Reliant Pharmaceuticals-Gave an overview of InnoPran XL.

Dr. Patel on behalf of GSK testified for Coreg. Mark Morack, GSK. Gave an overview of Coreg. David Nielsen, GSK. Gave an overview of Coreg.

Kate Ryan, Astra Zeneca-Gave an overview of Toprol XL. Dr. Heard asked if there was an indication for Class IV heart failure. Her response was no. Dr. Horne asked if there were any head to head studies with Coreg. Her response was no.

At this time Tom Wiser had to leave.

Jeff Monaghan gave an overview of all the beta-blockers. Dr. Phillips wanted to know if they should separate the class by adrenergic activity. Dr. Phillips stated they could determine therapeutic equivalency with prior authorization(PA) exceptions brought back for certain disease states, such as CHF based on New York heart classifications. Jeff Monaghan suggested the committee make a motion that the class be therapeutically equivalent. Exceptions could be handled via the PA process. Dr. Heard stated the prescriber could write a prescription with no justification or fill out the PA form and provide justification. Dr. Horne stated that one agent has antidepressant effects and wanted to know if all the generics would be on the PDL. Jeff Monaghan responded that most generics would be on the PDL.

XIII. Committee Discussion and Actions for Beta-Blockers (Oral)

Motion: Dr. Heard moved to approve the beta-blockers and combinations to be therapeutically equivalent as a class.

Second: Larry Pinson

Exclusions or exceptions: Dr. Phillips wanted to know if the congestive heart failure(CHF) would be an exception. Dr. Heard moved for a friendly amendment that CHF be an exception. Seconded by Larry Pinson. Dr. Horne moved for a friendly amendment for pediatric exceptions. Seconded by Larry Pinson.

Vote: Ayes: Unanimous (Tom Wiser & Dr. Pintar absent)

Criteria for Prior Authorization: None

XIV. Recess not taken at this time

XV. Presentation of DHCFP'S recommendations. Tabled at this time.

XVI. Approval of drugs to be included on the PDL. No recommendations from DHCFP as this time.

XVII. Public Comment

Dr. Heard requested that there be a one page process & procedure flow sheet so the committee would be on the same page about the P&T process.

Dr. Horne asked if the Drug Use Review board was designed to get around the P&T process. Mary Wherry, DHCFP, stated that Federal law mandates that the DUR board look at drug utilization prospectively and retrospectively and make recommendations. These recommendations can include step therapy.

The next P&T meeting is schedule for Thursday, April 22nd, 2004.

XVIII. Meeting adjourned at 4:30pm.